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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,471	08/15/2005	Peter Reynolds Foster	9013-67	7924
20792	7590	03/06/2006		
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER CARRILLO, BIBI SHARIDAN				
ART UNIT		PAPER NUMBER		
1746				

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/518,471

Applicant(s)

FOSTER ET AL.

Examiner

Sharidan Carrillo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/17/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. The disclosure is objected to because of the following informalities: The specification is objected to because it does not include the subheadings as described above

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite because it is unclear what one would consider as a further concentrated salt wash.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-8, and 10-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Prusiner (WO01/54736A2).

Prusiner teaches cleaning substrates in order to remove prions by washing with a salt solution (i.e. inorganic salt, protein denaturant) as described on page 7. In reference to claims 1 and 6-7, Prusiner teaches concentration ranges between 0.01-

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10% by weight for the protein denaturant, as described on page 15. In reference to claims 2-3 and 11, refer to page 5, lines 10-14. In reference to claims 4-5, refer to page 5, lines 14-20. In reference to claims 8 and 10, refer to page 7, lines 15-20.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 4-8, and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by McDonnell et al. (US2003/0086820).

McDonnell teaches a method of cleaning a surface to remove infected prions by treating with an alkaline cleaning solution. In reference to claims 1, 6-8 and 16-17, McDonnell teaches that the alkaline cleaning solution comprises EDTA salts having a concentration of about 1-15% by weight (paragraph 36). In reference to claims 4-5, refer to paragraph 2.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Gawryl et al. (5808011).

Gawryl teaches a 1.0M NaCl solution used for removal of prions from a chromatographic column.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonnell et al. (US2003/0086820).

McDonnell teaches a one step process of using the salt solution in combination with the alkali. McDonnell fails to teach a two step process of washing with a salt, followed by washing with an alkali. The splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner and result, was held not to be patentably distinguishable processes (Ex. Parte Rubin 128 USPQ 159 Po Bd Pat App 1959). Additionally, it would have been within the level of the skilled artisan to modify the method of McDonnell to include multiple cleaning steps using salt and alkaline solutions since paragraphs 97 and 98 of McDonnell teaches that the process can be combined with additional cleaning steps using various cleaning solutions. In reference to claim 13, refer to paragraph 96. In reference to claim 14, refer to paragraph 55. In reference to claim 15, refer to col. 4, line 1.

14. Claims 1-3, 6-9, and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uhlen et al. (6831161) in view of Gawryl et al. (5808011).

In reference to claims 1 and 17, Uhlen teaches cleaning and sanitizing chromatographic columns by washing with 0.1 to 1.0 M NaOH in combination with NaCl for removing prions (col. 2, lines 1-15). Uhlen teaches the invention substantially as claimed with the exception of the concentration of the NaCl solution. Gawryl et al. teach a method for removing prions from chromatographic columns. In col. 4, lines 28-31, Gawryl teaches using buffers such as 1.0M NaCl to elute the prion from the column. It would have been obvious to a skilled artisan to modify the method of Uhlen to include

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1.0 M NaCl, as taught by Gawryl, for purposes of eluting prions from the column. In reference to claims 6-7, it would have been well within the level of the skilled artisan to determine what concentration levels of NaCl solution are needed in order to elute the prions from the chromatographic column. In reference to claims 2-3 refer to col. 1-2 of Uhlen. In reference to claim 1, Uhlen teaches a chromatographic column. In reference to claim 12, Uhlen fails to teach a two step process of washing with a salt, followed by washing with an alkali. The splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner and result, was held not to be patentably distinguishable processes (Ex. Parte Rubin 128 USPQ 159 Po Bd Pat App 1959). In reference to claim 13, refer to col. 2, lines 10-11 of Uhlen. In reference to claim 14, Uhlen fails to teach a pH of at least 12. However, it would have been obvious and within the level of the skilled artisan to include a pH of at least 12 since Uhlen teaches an alkaline pH and extreme pH values using NaOH cleaning (col. 2, lines 20-23). In reference to claim 15, refer to col. 2, lines 14-15. In reference to claim 16, the limitations are met in view of the indefiniteness.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Prusiner et al. teach SDS for inactivating prions. Lynch teaches ozone sterilization of prions. Spittler teaches inactivating prions. Cunanan et al. teach treatment of instruments. Kross et al. disinfecting compositions. Prusiner teaches removal of prions from the blood. Antloga et al. teaches prionocidal activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharidan Carrillo whose telephone number is 571-272-

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1297. The examiner can normally be reached on M-W 6:30-4:00pm, alternating Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on 571-272-1414. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharidan Carrillo
Primary Examiner
Art Unit 1746

bsc



SHARIDAN CARRILLO
PRIMARY EXAMINER